

## **Remarks**

This is in reply to the official action of June 8, 2009 and the USPTO Office Communication of January 12, 2010.

In view of the Examiner's comments it is assumed that the Applicants need to take no further action with respect to the restriction/election requirement. The Applicants elected the particular lipid conjugate in the prior response, i.e. specific lipid conjugate galactocerebrosides.

Further claims 13-15 and 17-36 have been acted on by the Examiner, the only withdrawn claim being claim 16.

The traverse is maintained because the Examiner's statement as to why there is no unity of invention is insufficient. The Examiner says that a special technical feature of a "cosmetic composition comprising a lipid conjugate consisting of sphingolipids, galactolipids, and mixtures thereof, and a fluorocarbon" on the basis of an obviousness rejection based upon Unger, Felke et al and Schmidt. This is improper in that the present invention is not obvious in view of the cited references for the reasons subsequently discussed. For this reason it is clear that claim 16 should be rejoined.

Claims 33-36 have been rejected under 35 U.S.C. 112 for lack of antecedent basis "1,2-propylene glycol, glycerin, sphingolipid-oil/wax solution, PEG 75-shea butter, perfluorodecalin and water.

This rejection is improper and should be withdrawn.

Parent claim 13 uses the term "comprises" and is thus open ended to additional components, e.g. as listed in dependent claims 33-36. With the term "comprises" there is no need to list alcohol or PEG-75 Shea Butter or water in parent claim 13.

Claims 13-15 and 17-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (U.S. Patent 5,705,187) and Felke et al. (WO 95/20945) and Schmidt (U.S. Patent 5,776,470).

Per the above Office Communication, it seems the Examiner intends DE 4327679 as the reference to be combined with Unger. The Examiner refers to this reference as Felke, however, Felke is the prosecuting agent (Vertreter) rather than an inventor. The first named inventor is Zastrow.

The Unger reference is directed to a composition comprising “stable” vesicles containing a gas, i.e. a free gas, that is injected intravenously to provide an enhanced ultra sound image. (see e.g. Unger column 3, lines 4-62, and column 5, lines 1-46; column 22, lines 8-11) Toward this end, Unger requires a strong vesicle stabilizer. This is completely contrary to and teaches away from the present invention where the vesicles are formed to release oxygen into the skin instead of retaining a gas as taught by Unger. (See e.g. Unger Column 3, lines 65-67 and all of column 4) (See the present specification page 7, paragraph [0022]. Unger does not disclose or suggest a vesicle having a vesicle membrane of sphingolipids, galactolipids, or mixtures thereof that is less stable than a vesicle with a phospholipids membrane wherein the vesicle will release oxygen to tissue upon penetration of the skin.

It should also be pointed out that the Examiner picked and chose separate disclosures within Unger based entirely upon the Applicant’s disclosure.

Unger discloses no fewer than 50 possible lipid type materials for forming a membrane and discloses no fewer than 50 possible stabilizers as Unger requires. The permutations for making a selection of components within Unger using only those two components is thus more than 2500 and when other components taught or suggested by Unger are included, there are literally millions of possibilities. It was simply not obvious to one skilled in the art to pick a combination of various components within Unger to obtain the present invention especially since the picking of desired components would be exactly contrary to reasons given by Unger for making particular choices, i.e. high stability of vesicle containing gas for purposes of imaging contrary to the present invention where such high stability is detrimental to release of oxygen to tissues. Unger thus teaches away from the present invention. Unger thus clearly does not disclose or suggest the critical combination of components of the presently claimed invention. Any such combination could only be made by unsupported and improper hindsight after first learning about the invention from the present application.

The Zastrow et al. reference (DE 4327679) does nothing to cure the critical defects of Unger. Zastrow discloses compositions requiring phospholipids. **There is no disclosure or suggestion in either reference for using sphingolipids, galactolipids and mixtures thereof.**

As previously discussed, phospholipids vesicles are very stable and thus do not readily release oxygen to surrounding tissue as is the case with sphingolipids and galactolipids in

accordance with the presently claimed invention. Zastrow et al. describes product that are lamellar aggregates but these should not be properly called vesicles.

As previously discussed, stable phospholipids vesicles have previously been desired as described in Unger et al. but are undesirable in the present invention. The use of relatively unstable sphingolipids and galactolipids to form vesicles in accordance with the present invention is not suggested by any of the cited references alone or in any combination.

There is no suggestion in either Unger or Zastrow et al. of the use of sphingolipids or galactolipids to obtain weak vesicles.

Reference may be had, in the present application, to the Background of the Invention, The Brief Description of the Invention, Paragraph [0022] and the Examples and Table in the Detailed Description of the Invention, detailing the desirability of vesicles that will release oxygen upon penetration of the skin.

The cited Schmidt reference does absolutely nothing to cure the critical defects of Unger et al. and Schmidt does not even relate to vesicles and certainly does not relate to vesicles having a sphingolipid and/or galactolipid membrane containing a fluorocarbon charged with oxygen and suggests nothing at all concerning improved oxygen transport.

All rejections of other claims, all of which carry the limitations of Claim 13, are defective for the same reasons given above. All remaining rejections rely upon Unger, which is defective for reasons previously discussed and upon Felke (Zastrow et al), which also uses phospholipids, not sphingolipids, galactolipids and mixtures thereof. If Zastrow easily releases oxygen, as is the case with the present invention, it does not do so with sphingolipids, galactolipids and mixtures thereof. If Zastrow et al. easily releases oxygen, it must be by some other more complex process, e.g. by avoiding vesicles, by using cellular breakdown products and/or particular carriers. Zastrow certainly does not suggest sphingolipids, galactolipids and mixtures thereof for that purpose.

None of the additionally cited references cure the critical defects presented by Unger and Zastrow et al. Further, none of the references suggest anything or any way in which oxygen transport into the skin can be improved by a novel vesicle having a sphingolipid and/or galactolipid membrane containing a fluorocarbon charged with oxygen that readily releases the oxygen when entering the skin.

Amendments to the specification are made to correct inadvertent typographical type errors.

The amendments to the fourth paragraph on page 9 of the specification are supported by original claim 9 (amended claim 30) and by examples 1 and 2 of the original specification.

The amendment to claim 32 (original claim 11) is supported by the first full paragraph on page 10, lines 6-10 of the specification and appeared in the specification as originally filed.

All claims are patentable over the current rejections as previously discussed and all formalities have been corrected. All claims are, therefore, now in condition for allowance, which action is courteously requested.

Respectfully submitted,

/Michael L. Dunn/

Michael L. Dunn  
Registration No. 25330  
CUSTOMER NO. 49003  
Simpson & Simpson, PLLC  
5555 Main Street  
Williamsville, NY 14221-5406  
Telephone No. 716-626-1564

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MLD/MJK